I hereby certify that this correspondence is being facsimile transmitted to the United States Patent and Trademark Office, Fax No. 703-872-9307 on the date set forth below.

Date of Signature
And Fax Transmittal: June 25, 2003

Barbara J. Luther

Barbara J. Luther, Registration No. 33,954

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Michael McGrogan et al., *et al.*

Serial No.: 09/494,088

Filed: January 28, 2000

For: Production and Use of Dopaminergic Cells to Treat Dopaminergic Deficiencies

Group Art Unit: 1643

Examiner: Ann-Marie Falk, Ph.D.

Docket No.: LAY-006C1A

Considered 7/17/03. Amd.

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. 1.132

BY INVENTOR MICHAEL McGROGAN, Ph.D.

Dear Examiner.

I am an inventor of the above-captioned subject matter. I have a Ph.D. in Molecular and Cell Biology from Washington University Medical School (St. Louis, Missouri) and did postgraduate work at Stanford University, Stanford, California. I have been involved in cell culturing techniques for over 30 years. I am an employee of Layton BioScience, Inc., the

postgraduate work at Stanford University, Stanford, California. I have been involved in cell culturing techniques for over 30 years. I am an employee of Layton BioScience, Inc., the assignee of this invention. With reference to the above-captioned patent application, I state the following:

1. I am familiar with the above-captioned patent application. I have reviewed the Office Action mailed January 17, 2003. I am also familiar with the cited reference: Baker et al., Intrastriatal and Intranigral Grafting of hNT Neurons in the 6-OHDA Rat Model of Parkinson's Disease. **Exp. Neurol. 162**:350-60, 2000. I reviewed the paper before it was accepted. As indicated on the first page of the reprint, the paper was initially received by the journal on August 27, 1999 and was accepted on December 6, 1999.

2. We supplied Dr. Baker with the dopaminergic cells of two types ("hNT-DA neurons" and LiCl pretreated hNT-DA neurons in the paper), as well as other control hNT neurons, in 1998 to be evaluated in the rat 6-OHDA model which correlates with human Parkinson's disease. Dr. Baker in turn provided us with the data reported in the above-mentioned reprint and used in example 12, starting on page 28 of the instant patent application. The cells we provided to Dr. Baker were induced from NT2/D1 cells by the method of Example 4, and were not genetically engineered

3. The data from Dr. Baker showed that in animals where there were surviving hNT-DA cells (43% of the animals transplanted therewith) and surviving LiC1 pretreated hNT-DA neurons (100% of the animals transplanted therewith), all animals "had decreased rotational scores while animals with no surviving THir cells (hNT-neuronal grafts and lesion only groups) did not exhibit any reduction in mean full body turns" (pages 354-5 of the Baker article).

4. Therefore, I believe it is shown that the hNT-DA cells are capable of positively affecting rotational scores in the rat 6-OHDA model for human Parkinson's disease.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that I understand that making willful false statements and the like constitutes conduct punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code, and that any such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Respectfully submitted,

Dated: June 25 2003

By: _____

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